

patentability over the obviousness rejection. First, the Selker I, Heemels, and Brown patents, taken as a whole, still do not provide a suggestion, motivation, or reason to combine. “The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination.” MPEP § 2143.01 (citing *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990)). That Selker I, Heemels and Brown all allegedly monitor a patient’s health status to provide patient care is not sufficient to demonstrate the desirability of combining their respective teachings.

10 In the asserted combination, Selker I is alleged to disclose the claimed invention, except for an implantable monitoring device, and is therefore combined with Heemels, which is stated to provide the implantable medical device. Combining the teachings of Selker I with the teachings of Heemels assumes that the patient is a recipient of an implantable monitoring device. However, Selker I
15 teaches continuous monitoring of ambulatory patients using a predictive instrument. In particular, Selker I teaches a medical instrument, which during use, is connected to the patient to monitor one or more clinical features and a predictive instrument receiving output from the medical instrument (Col. 1, lines 59-67). Selker I teaches that the medical instrument is a 12-lead
20 electrocardiograph (ECG) and a waveform analyzer programmed to analyze ECG waveforms to recognize the presence of certain characteristics that are particularly indicative of the cardiac condition of the patient (Col. 2, lines 49-60). Selker I further teaches an electrocardiograph and waveform analyzer that is commercially available as a single unit, in the form of a mobile unit that can be moved from one
25 patient to the next (Col. 3, lines 12-24). In addition, Selker teaches that the computer within the mobile unit can also be programmed to perform the functions of other components, such as computations of the predictive instrument (Col. 3, lines 24-29). Moreover, Selker teaches that the system is programmed to be operated by a physician for a particular patient, which includes connecting the
30 leads of the ECG to the patient and performing an initial ECG (Col. 3, line 64- Col. 4, line 14). In addition, Selker I specifically teaches monitoring ambulatory

patients and provides four examples of actual patient histories, each of which are evaluated in the context of an emergency department (Col. 6, line 33-Col. 8, line 15). Thus, Selker I fails to suggest the desirability of combining with an implantable monitoring device.

5 Second, even when combined by picking and choosing selected parts, the Selker I, Heemels, and Brown patents do not teach or suggest all claim limitations when considered in light of the disclosure of each respective patent. In the asserted combination, Selker I, as modified by Heemels, is alleged to disclose the claimed invention, except for storing all monitored data and monitoring and
10 recording quality of life measurements, and is therefore combined with Brown, which is stated to provide storing all monitored data and monitoring and recording quality of life measurements. However, Claim 1 recites “a quality of life comparison submodule comparing the updated quality of life measures to the reference quality of life measures in the patient care record to generate the patient
15 status indicator identifying any such substantially non-conforming updated quality of life measure.” Claim 10 recites “comparing the updated quality of life measures to the reference quality of life measures in the patient care record to generate the patient status indicator identifying any such substantially non-
20 conforming updated quality of life measure.” Claim 20 recites “a quality of life comparison submodule comparing the updated quality of life measures to the reference quality of life measures in the patient care record and identifying any such updated quality of life measure substantially non-conforming to the corresponding reference quality of life measures as part of the patient status
25 indicator.” And Claim 25 recites “comparing the updated quality of life measures to the reference quality of life measures in the patient care record and identifying any such updated quality of life measure substantially non-conforming to the corresponding reference quality of life measures as part of the patient status
30 indicator.” Such claim limitations are neither taught nor suggested by the asserted combination of Selker I, Heemels, and Brown.

Finally, if combined, the Selker I, Heemels, and Brown patents do not provide a reasonable expectation of success. Selker I further teaches a control

module causing the predictive instrument to periodically repeat the monitoring cycle and computing therefrom a change-of-condition measure (Col. 2, lines 3-7).

Heemels teaches an implantable stimulator that processes and logs multiple sets of two-dimensional histogram data for sensed beat intervals limited to a 24-hour period (Col. 2, lines 28-31; Col. 3, lines 9-26). In combination, the teachings of Selker I, Heemels, and Brown would provide a control module *external to* the implantable stimulator that would indirectly cause periodic repetition of the monitoring cycle, in contrast to the “one or more updated physiological measures regularly recorded by the implantable medical device” recited in Claim 1, “one or more updated physiological measures regularly recorded by the implantable medical device” recited in Claim 10, “one or more updated physiological measures recorded by the implantable medical device” recited in Claim 20, and “one or more updated physiological measures recorded by the implantable medical device” recited in Claim 25. Thus, there would be no reasonable expectation of success when combining Selker I, Heemels and Brown.

Thus, a *prima facie* case of obviousness still has not been shown with respect to Claims 1, 10, 20, and 25. Claims 2-5 are dependent on Claim 1 and are patentable for the above-stated reasons, and as further distinguished by the limitations recited therein. Similarly, Claims 11-14 are dependent on Claim 10 and are patentable for the above-stated reasons, and as further distinguished by the limitations recited therein. Claims 21-23 are dependent on Claim 20 and are patentable for the above-stated reasons, and as further distinguished by the limitations recited therein. Claims 26-28 are dependent on Claim 25 and are patentable for the above-stated reasons, and as further distinguished by the limitations recited therein. Accordingly, as a *prima facie* case of obviousness has not been shown for Claims 1-5, 10-14, 20-23 and 25-28, withdrawal of the rejection for obviousness under 35 U.S.C. 103(a) is requested.

Claims 7-9 and 16-18 rejected under 35 U.S.C. 103(a) as being obvious over Selker I, in view of Heemels, and further in view of Brown, and further in view of U.S. Patent No. 4,852,570, to Levine (“Levine”). Applicant traverses the rejection.

Claims 7-9 are dependent on Claim 1 and are patentable for the above-stated reasons, and as further distinguished by the limitations recited therein.

Claims 16-18 are dependent on Claim 10 and are patentable for the above-stated reasons, and as further distinguished by the limitations recited therein.

5 Accordingly, as a *prima facie* case of obviousness has not been shown for Claims 7-9 and 16-18, withdrawal of the rejection for obviousness under 35 U.S.C. 103(a) is requested.

Claims 19 and 30 are rejected under 35 U.S.C. 103(a) as being obvious over Selker I, in view of Heemels, in view of Brown, and further in view of
10 Levine, and further in view of U.S. Patent No. 6,067,466, to Selker et al. ("Selker II"). Applicant traverses the rejection.

Claim 19 is dependent on Claim 10 and is patentable for the above-stated reasons, and as further distinguished by the limitations recited therein. Similarly, Claim 30 is dependent on Claim 25 and is patentable for the above-stated reasons,
15 and as further distinguished by the limitations recited therein. Accordingly, as a *prima facie* case of obviousness has not been shown for Claims 19 and 30, withdrawal of the rejection for obviousness under 35 U.S.C. 103(a) is requested.

The prior art made of record and not relied upon has been reviewed by the applicant and is considered to be no more pertinent than the prior art references
20 already applied.

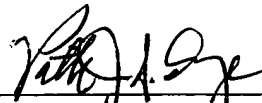
Claims 1-5, 7-14, 16-23, 25-28, and 30 are believed to be in condition for allowance. Entry of the foregoing amendment is requested and a Notice of Allowance is earnestly solicited. Please contact the undersigned at (206) 381-3900 regarding any questions or concerns associated with the present matter.

25

Response to Non-Final Office Action
Docket No. 020.0220.US.CON

Respectfully submitted,

5 Dated: October 22, 2004

By: 
Patrick J.S. Mouye, Esq.
Reg. No. 40,297

10 Law Offices of Patrick J.S. Inouye
810 Third Avenue, Suite 258
Seattle, WA 98104

Telephone: (206) 381-3900
Facsimile: (206) 381-3999

OA4 Response